UNITED STATES DISTRICT COURT

for the District of Maine

In the Matter of the Search of				
(Briefly describe the property to be or identify the person by name and	address)	Case No. 22 2	?-mj-198-NT	
Merideth C. Norris, P.A., d/b/a Gra located at 58 Portland Road Kennebunk, Maine 04	, Suite 18			
APPLICATION FOR A WARR	ANT BY TELEPHONI	E OR OTHER RELIA	ABLE ELECTRONIC MEANS	
I, a federal law enforcement penalty of perjury that I have reason property to be searched and give its location,	to believe that on the foll	the government, reque owing person or prope	est a search warrant and state under rty (identify the person or describe the	
See Attachment A				
located in the	District of	Maine ,	there is now concealed (identify the	
person or describe the property to be seized):				
See Attachment B				
The 1 1 Co. (1 1 1 1 1	F 1 P C' - P 41()			
The basis for the search under evidence of a crime;	er Fed. R. Crim. P. 41(c)	IS (check one or more):		
contraband, fruits of crime, or other items illegally possessed;				
property designed for use, intended for use, or used in committing a crime;				
a person to be arrested	ed or a person who is unla	awfully restrained.		
The search is related to a vio	lation of:			
Code Section				
18 U.S.C. 1347	Health Care Fraud			
21 U.S.C. 841(a)(1)	Illegal Drug Distribution	П		
The application is based on the	hese facts:			
See attached affidavit.				
☐ Continued on the attache	d sheet			
Delayed notice of		if more than 30 days:) is requested under	
	asis of which is set forth			
	W.	Ab	plicant's signature	
		SAI	Dale Wengler FBI	
		Pri	inted name and title	
Sworn to telephonically and signed			TATES DISTAL	

Sworn to telephonically and signed electronically in accordance with the requirements of Rule 4.1 of the Federal Rules of Criminal Procedures

Date: Oct 25 2022

City and state: Portland, Maine

Nancy Torresen, U.S. District Judge

Printed name and title

Judge's signature

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

THE SEARCH OF MERIDETH C. NORRIS, P.A., d/b/a GRACEFUL RECOVERY, located at 58 PORTLAND ROAD, SUITE 18, KENNEBUNK, MAINE 04043

Case No. 2:22-mj-198-NT

Filed Under Seal

AFFIDAVIT IN SUPPORT OF SEARCH WARRANT

Special Agent Dale Wengler, being duly sworn, deposes and says:

I. <u>INTRODUCTION AND AGENT BACKGROUND</u>

- 1. I, Dale Wengler, am a Special Agent with the Federal Bureau of Investigation ("FBI") and have been for over eleven years. As an FBI Special Agent, I have investigated crimes involving civil rights, crimes against children, public corruption, health care fraud, and white-collar criminal matters. I received training and gained experience in interviewing and interrogation techniques, arrest procedures, search warrant applications, the execution of searches and seizures, computer crimes, and various other criminal law procedures. I am a federal law enforcement officer who is engaged in enforcing federal criminal laws, and I am authorized by the Attorney General to request search and arrest warrants.
- 2. The FBI, along with the U.S. Drug Enforcement Administration ("DEA"), the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General (""HHS-OIG"), and the U.S. Department of Justice, Criminal Division, is investigating Dr. Merideth C. Norris ("NORRIS") for violations of federal law—including violations of 21 U.S.C. § 841(a)(1) (illegal drug distribution), 42 U.S.C. § 1320a-7b(b)(1)(A) (soliciting and receiving illegal kickbacks), and

¹ On October 20, 2022, the Grand Jury indicted NORRIS on ten counts of unlawful distribution of controlled substances, in violation of 18 U.S.C. § 841(a)(1), related to her prescribing—outside the usual course of professional practice and not for a legitimate medical purpose—for three patients, in case 2:22-cr-132-NT. The government is continuing to investigate her prescribing practices as well as other potential violations of federal law.

18 U.S.C. § 1347 (health care fraud)—related to her practices at: (i) Merideth C. Norris, PA, dba Graceful Recovery, located at 58 Portland Road, Suite 18, in Kennebunk, Maine 04043 (also known as "Mercy Recovery Center") ("TARGET LOCATION" or "GRACEFUL RECOVERY"); (ii) Savida Health, PC, located at 409 Alfred Street, Units 4–5, in Biddeford, Maine 04005 ("Savida Health"); (iii) Enso, LLC, dba Enso Recovery ("Enso Recovery"); and (iv) CAP Quality Care, Inc., located at 1 Delta Drive, in Westbrook, Maine 04092 ("CAP Quality"). 3

- 3. I am personally involved in this investigation along with other federal agents. The statements contained in this affidavit are based upon a review of both public and private records, subpoena returns, prescription data and Medicare and Medicaid claims data, and interviews conducted by me and other federal agents of witnesses knowledgeable about the facts underlying this investigation. Because this affidavit is provided for the limited purpose of establishing probable cause for a search warrant, it does not include every known fact concerning this investigation, but rather sets forth only those facts that I believe are necessary to establish probable cause.
- 4. This affidavit is made in support of an application for a search warrant under Rule 41 of the Federal Rules of Criminal Procedure in an ongoing federal criminal investigation into NORRIS authorizing the search and seizure of certain information and records maintained at NORRIS's practice, GRACEFUL RECOVERY (TARGET LOCATION) (as more fully

² Enso Recovery operates multiple opioid addiction programs throughout Maine, including four Medication Assisted Treatment recovery residences in Sanford and Augusta.

³ On August 25, 2022, in *In re Application of the United States for Ex Parte Orders in the Matter of Dr. Merideth C. Norris, M.D.*, No. 2:22-mc-00179-KFW, U.S. Magistrate Judge Karen Frink Wolf issued orders (under seal), pursuant to 42 C.F.R § 2.66 (authorizing use and disclosure of patient records) and 42 C.F.R. § 2.67 (authorizing undercover operations) related to GRACEFUL RECOVERY and Savida Health. On October 14, 2022, Magistrate Judge Wolf amended the orders to include CAP Quality and Enso Recovery.

described in Attachment A of this affidavit), to seize the fruits, evidence, and instrumentalities of criminal conduct (as more fully described in Attachment B).

- 5. Based on my training and experience and the facts as set forth in this affidavit, there is probable cause to believe that, from in or around January 1, 2019, and continuing through the present, in the District of Maine and elsewhere, NORRIS has violated, and is continuing to violate, 21 U.S.C. 841(a)(1) (illegal drug distribution), 42 U.S.C. § 1320a-7b(b)(1)(A) (soliciting and receiving illegal kickbacks), and 18 U.S.C. § 1347 (health care fraud) (collectively the "TARGET OFFENSES"). Specifically, this investigation relates to NORRIS's involvement in: (i) illegal drug distribution and drug diversion by prescribing controlled substances outside the ordinary course of professional practice to individuals with no legitimate need for the controlled substances, many of whom engage in drug-seeking behavior; (ii) submitting claims to Medicare and Medicaid for medically unnecessary services; and (iii) soliciting or receiving kickbacks from laboratories in exchange for referring laboratory services (urine drug screening and testing).
- 6. As a result, there is probable cause to believe that evidence, fruits, and instrumentalities of the TARGET OFFENSES are located at the **TARGET LOCATION**.

II. RELEVANT ENTITIES AND INDIVIDUALS

- 7. MERIDETH C. NORRIS is a Doctor of Osteopathic Medicine, licensed by the State of Maine Board of Osteopathic Licensure, under license number #1813, to practice medicine in the State of Maine. She is registered with the DEA to prescribe controlled substances under registration numbers: BN7421441 and XN7421441. As described below, NORRIS is authorized under the Drug Addiction Treatment Act of 2020 ("DATA") to treat up to 275 patients for addiction treatment. She is also enrolled as a provider in both the Medicare and Medicaid health care benefit programs.
- 8. The **TARGET LOCATION** is located at 58 Portland Road, Suite 18, Kennebunk, Maine.
- 9. CAP Quality is opioid treatment program where, according to Medicare enrollment records, NORRIS is an officer. According to banking records, NORRIS received bi-monthly payments from CAP QUALITY.
- 10. Enso Recovery operates opioid addiction and medication assisted recovery residences in Augusta, Maine and Sanford, Maine. According to Enso Recovery's website (mainesuboxone.com/index.php/about-enso-recovery/ (last visited October 19, 2022)), NORRIS is Enso Recovery's medical director.
- 11. Savida Health operates an opioid addiction treatment center from which, according to bank records, NORRIS receives a monthly deposit.
- 12. Millennium Laboratories, Inc. ("Millennium") is a clinical medical laboratory enrolled with Medicare and MaineCare (Medicaid). NORRIS referred urine drug screening and testing to Millennium for patients NORRIS treated at the **TARGET LOCATION** and for whom she prescribed controlled substances.

III. FACTUAL BACKGROUND

Controlled Substances Act

- 13. The Controlled Substances Act ("CSA") governs the manufacture, distribution, and dispensing of controlled substances in the United States. *See* 21 U.S.C. § 801, *et seq*. It is a federal offense for any person to knowingly or intentionally distribute or dispense a controlled substance except as authorized by law. *See* 21 U.S.C. § 841(a)(1). It is similarly a federal offense to conspire to violate Section 841(a)(1). *See* 21 U.S.C. § 846. The DEA was established in 1973 to serve as the primary federal agency responsible for the enforcement of the CSA.
- 14. 21 U.S.C. § 812 establishes Schedules for controlled substances that present a potential for abuse and the likelihood that abuse of the drug could lead to physical or psychological dependence on it. Such controlled substances are listed in Schedule I through Schedule V, depending on the level of potential for abuse, the current medical use, and the level of possible physical dependence. Controlled substance pharmaceuticals are listed as controlled substances, from Schedule II through V, because they are also considered drugs for which there is a substantial potential for abuse and addiction.
- 15. Legitimate transactions involving pharmaceutical controlled substances take place within a "closed system" of distribution established by Congress. Under the "closed system," Title 21 of the United States Code requires that all legitimate handlers of controlled substances (including manufacturers, distributors, physicians, pharmacies, and researchers) be registered with the DEA and maintain strict accounting for all distribution.
- 16. Legitimate distributions of controlled substances are limited by the scope of each type of registration. 21 U.S.C. § 802(21) defines a "Practitioner" to include physicians and other medical professionals licensed, registered, or otherwise permitted by the United States or the

jurisdiction in which he practices or does research to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

- 17. Medical professionals, including physicians, must become registered with the Attorney General to be authorized under the CSA to write prescriptions for, or to otherwise distribute or dispense, controlled substances, as long as they comply with requirements under their registration. 21 U.S.C. § 822(b). Such medical professionals are then assigned a registration number with the DEA.
- 18. To comply with the terms of their registration, medical professionals cannot issue a prescription for a controlled substance unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Section 1306.04(a) provides that:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the Controlled Substances Act (Title 21, United States Code, Section 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions relating to controlled substances.

Id.

Characteristics of Illegal Prescribing Practices

19. Dosage in one or multiple concurrently prescribed opioids is measured through Morphine Milligram Equivalents ("MME"). MME measures a patient's daily dosage of opioids, based upon a conversion factor of the strength of the opioid (using morphine as a base of 1) and the quantity of the controlled substance prescribed per day. The U.S. Centers for Disease Control

and Prevention ("CDC") have medically determined the relative strength of opioids and made the list publicly available. For example: a patient who is prescribed and ingests a single milligram of morphine once a day will have a 1 MME over the life of the prescription. However, a patient who ingests prescribed oxycodone (at a conversion factor of 1.5 MME) in the standard prescription of 5 milligram dose four times a day will have a 30 MME over the life of that prescription. Some medical professionals refer to opioid dosage calculations as MED or MEQ. MME, MED, and MEQ are all interchangeable terms that relate to the same calculation.⁴

- 20. On August 31, 2016, the U.S. Food and Drug Administration ("FDA") issued notice about the danger of concurrent opioid and benzodiazepine prescribing. In this notice, the FDA explains the dangers of concurrently prescribing opioids, benzodiazepines, and other central nervous system depressants, because concurrent use of these controlled substances can result in coma and even death. The FDA—noting that opioids alone carry serious risks such as abuse, addiction, overdose, and death—also cited multiple studies confirming these findings, including one which concluded that patients are at ten times higher risk of overdose death through concurrent use of opioids and benzodiazepines. The FDA strongly warns practitioners to limit these concurrent prescriptions, dosages, and duration of each drug to the minimum possible, due to the danger of patient harm by concurrent dosages.
- 21. 21 U.S.C. § 841(a)(1) makes it an offense for any person to knowingly and intentionally distribute or dispense a controlled substance except as authorized by law. Analyzing this issue often turns on the facts of a particular case. There are nonetheless red flags that are

⁴ On February 10, 2022, the CDC made available for public comment a draft updated Clinical Practice Guideline for Prescribing Opioids. The CDC is expected to issue the final clinical practice guideline by the end of 2022. *See* Centers for Disease Control and Prevention, Process for Updated the Opioid Prescribing Guideline, available at https://www.cdc.gov/opioids/guideline-update/index html (last visited September 9, 2022).

indicative of prescriptions that are not issued for a legitimate medical purpose, some of which are discussed below.

- 22. I know through my training and experience, and through consultation with experts in the field, that characteristics of illegal pain management clinics or "pill mills" that dispense controlled substances outside the scope of professional practice and not for a legitimate medical purpose include:
 - a. the clinic accepts cash only, or accepts cash as a main method of payment;
 - the patients receive prescriptions for the same or similar combinations of controlled substances;
 - c. the patients receive no physical examination (or a very cursory examination is conducted);
 - d. the doctors at the clinic pre-sign prescriptions for controlled substances;
 - e. the physician prescribes or dispenses an inordinately large quantity of controlled substances;
 - f. the physician prescribes or dispenses dangerous combinations of controlled substances that appear to have little to no legitimate medical purpose or justification;
 - g. the doctors at the clinic fail to treat patients with anything other than controlled substances (e.g., the clinician never recommends physical therapy, surgery, massage therapy, etc.);
 - h. the doctors at the clinic fail to heed warnings about patients by others (insurance companies, pharmacists, family members, or clinicians); and
 - i. clinics are not certified or accredited under the appropriate state laws.

Drug Addiction Treatment Act of 2000 (DATA) Waiver

- Under the provisions of the CSA, 21 U.S.C. §§ 801-971, the DEA registers medical practitioners who dispense narcotic drugs to individuals for "maintenance treatment or detoxification treatment." 21 U.S.C. § 823(g). "Maintenance treatment" is defined as the "dispensing, for a period in excess of twenty-one days, of narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drugs." 21 U.S.C. § 802(29). "Detoxification treatment" is defined as the "dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to the withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period." 21 U.S.C. § 802(30).
- 24. The practitioner seeking such a registration must be qualified and abide by DEA statutes and regulations, as well as the statutes and regulations of HHS. 21 U.S.C. § 823(g)(1). Furthermore, the applicant must be qualified and willing to "comply with the standards established by the Secretary [of HHS] . . . respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment." 21 U.S.C. § 823(g)(1)(C).
- 25. In 2000, Congress passed the Drug Addiction Treatment Act (DATA), Pub. L. No. 106-310, 114 Stat. 1222 (codified at 21 U.S.C. §823(g)). Under the DATA, Congress waived the requirements under Section 823(g)(1) for practitioners who dispense and administer narcotic drugs in Schedule III, IV, and V (but not Schedule II) for maintenance of detoxification treatment, subject to certain conditions. 21 U.S.C. § 823(g)(2)(A). Practitioners who obtain a waiver pursuant to Section 823(g)(2) are known as "DATA-waived physicians" or office-based opioid treatment ("OBOT") physicians.

26. Currently, the only controlled substance approved by the FDA for dispensing and administering by OBOT physicians to narcotic addicted patients is buprenorphine, the generic name for Suboxone and Subutex, a Schedule III controlled substance. 42 C.F.R. § 8.12(h)(2)(iii); 21 C.F.R. § 1308.13(e). In addition, the DATA limits the number of narcotic-addicted patients that can be treated at one time by an OBOT physician to 30, 100, or 275 patients. 21 U.S.C. § 823(g)(2)(B)(iii). In this instance, NORRIS is a DATA-waived medical professional who is authorized to treat up to 275 office-based opioid treatment patients pursuant to the requirements of Section 823(g)(2).

Relevant Controlled Substances

Opioids

- Opioids are controlled substances that vary from Schedule I to Schedule V, depending on their medical usefulness, abuse potential, safety, and drug dependence profile. Opioids are prescribed by doctors to treat pain, suppress cough, cure diarrhea, and put people to sleep. Effects depend heavily on the dose, how it's taken, and previous exposure to the drug. Negative effects include slowed physical activity, constriction of the pupils, flushing of the face and neck, constipation, nausea, vomiting, and slowed breathing. As the dose is increased, both the pain relief and the harmful effects become more pronounced. Some of these preparations are so potent that a single dose can be lethal to an inexperienced user.
- 28. Schedule I narcotics, such as heroin, have no medical use in the U.S. and are illegal to distribute, purchase, or use outside of medical research. In addition, Schedule I controlled substances have a very high potential for abuse and addiction.

29. Schedule II controlled substances have a high abuse/addiction potential, yet there is a current medical use in treatment so long as the clinician practices extreme caution. Schedule II opioids include oxycodone, methadone, and morphine.

Benzodiazepines

- 30. Benzodiazepines are Schedule IV⁵ depressants that will put you to sleep, relieve anxiety and muscle spasms, and prevent seizures. Benzodiazepines share many of the undesirable side effects of opioids, including tolerance and dependence. Individuals abuse depressants to experience euphoria. Depressants are also used with other drugs to add to the other drug's high. Unfortunately, when used in combination with opioids, depressants not only add to the opioid's high, but the combination also increases the potential of negative side effects, such as slowed breathing, known as respiratory depression. Some examples of benzodiazepines are Valium (diazepam), Xanax (alprazolam), and Klonopin (clonazepam).
- 31. Alprazolam, for example, is a generic name for a Schedule IV benzodiazepine prescription drug. Alprazolam is marketed primarily under the brand name Xanax. When used for a legitimate medical purpose, Xanax is used to treat such conditions as anxiety, depression, and panic disorder. Alprazolam comes in .25 mg, .5 mg, 1 mg, and 2 mg strengths. The 2 mg tablets are rectangular in shape and are often referred to on the street as "bars" or "zanny bars." Alprazolam can be addictive and is a commonly abused controlled substance that is diverted from legitimate medical channels.

⁵ Schedule IV controlled substances have less potential for abuse and addiction than Schedule II controlled substances and have a current medical use. Schedule IV controlled substances can still be abused and are dangerous when prescribed simultaneous to other controlled substances.

Amphetamines

- 32. Amphetamines are stimulants, most often used to treat attention-deficit hyperactivity disorder and narcolepsy. Because of their high potential for abuse, many amphetamines are Schedule II stimulants. Prolonged use of amphetamines has a high risk of drug dependence. Misuse of amphetamine can cause serious cardiovascular issues, as well as death.
- 33. Dextroamphetamine-amphetamine, for example, is a form of Schedule II stimulant prescription drug. Dextroamphetamine-amphetamine is marked primarily under the brand name Adderall. When used for a legitimate medical purpose, Adderall is used to treat such conditions as ADHD and narcolepsy. Dextroamphetamine-amphetamine comes in 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, and 30 mg tablets and 5 mg, 10 mg, 15 mg, 20, mg, 25 mg, and 30 mg extended-release capsules. Dextroamphetamine-amphetamine can be addictive and is a commonly abused controlled substance that is diverted from legitimate medical channels.

Buprenorphine

- 34. Buprenorphine is a Schedule III⁶ medication approved by the FDA to treat Opioid Use Disorder ("OUD") as a medication-assisted treatment ("MAT"). As with all medications used in MAT, buprenorphine should be prescribed as part of a comprehensive treatment plan that includes counseling and behavioral therapies. Buprenorphine can be prescribed or dispensed in physician offices.
- 35. Buprenorphine is a partial opioid antagonist that binds with opioid receptors in the brain that cause reduced pain and feelings of wellbeing. While buprenorphine isn't a full opioid, it acts like one, causing moderate receptor site activity. When taken as directed, buprenorphine does not create a euphoric state.

⁶ Schedule III controlled substances are drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.

- 36. Buprenorphine products approved by the FDA for treatment of OUD include buprenorphine sublingual tablets (Subutex) and buprenorphine sublingual films (Suboxone), among others. The main difference between Suboxone and Subutex is that Suboxone contains both buprenorphine and naloxone, while Subutex contains only buprenorphine. Naloxone is an opioid antagonist, which blocks the effects of opioids at the receptor site. As a result, based on my training and experience, I know that Subutex is more prone to be abused or diverted.
- 37. Based on my training and experience, many of the more powerful opioids, such as oxycodone, fentanyl, and methadone, are frequently abused by drug addicts and are highly addictive. In addition, based on my training and experience, many drug-seeking patients also try to obtain prescriptions for benzodiazepines, such as alprazolam, lorazepam, clonazepam, or diazepam. I am aware that drug users refer to the combination of an opiate and a benzodiazepine as a "drug cocktail." I am also aware, based on my training and experience, that the addition of a benzodiazepine to an opiate intensifies the high for the user. If not monitored closely, the combination of opiates and benzodiazepine can cause death because they can significantly depress the central nervous system. Another important aspect of investigating drug diversion cases involves identifying patients who have died or overdosed as a result of ingesting the drugs prescribed by those doctors. Based on my training and experience, a high number of patient deaths or overdoses associated with a particular doctor may indicate that the doctor is prescribing outside the scope of legitimate medical practice.
- 38. Based on my training and experience investigating cases of unlawful prescription diversion, I know that a practitioner concurrently prescribing the aforementioned medications in certain combinations or in certain dosages is *not* prescribing for a legitimate medical purpose and is prescribing outside the usual course of professional practice. Prescribing and issuing these

medications around the same time greatly compounds the patient's risk of overdose and death from the prescribed drugs. Moreover, there is a significant diversion risk of prescribing or issuing these drugs contemporaneously. These substances serve as "potentiators" for the opioid's euphoric effect to increase the "high" a user may obtain from the opioid and are often sought for this illegitimate purpose.

Medical Benefit Programs

- 39. NORRIS is enrolled as a provider with Medicare and Medicaid and provides medical services to recipients of Medicare, Medicaid, and other health care benefit programs, as that term is defined in 18 U.S.C. § 24(b).
- 40. The Medicare Program ("Medicare") is a federally funded program that provided free and below-cost health care benefits to individuals, primarily the elderly, blind, and disabled. The benefits available under Medicare are governed by federal statutes and regulations. The United States Department of Health and Human Services ("HHS"), through its agency, the Centers for Medicare & Medicaid Services ("CMS"), oversees and administers Medicare. Individuals who receive benefits under Medicare were commonly referred to as Medicare "beneficiaries."
- 41. Medicare is a "health care benefit program," as defined by Title 18, United States Code, Section 24(b), and a "Federal health care program," as defined by Title 42, United States Code, Section 1320a-7b(f).
- 42. Medicare covers different types of benefits and was separated into different program "parts." Medicare "Part A" covers, among others, health services provided by hospitals, skilled nursing facilities, hospices, and home health agencies. Medicare "Part B" covers, among other things, medical items and services provided by physicians, medical clinics, laboratories, and other qualified health care providers, such as office visits, minor surgical procedures, durable

medical equipment ("DME"), and laboratory testing, that were medically necessary and ordered by licensed medical doctors or other qualified health care providers. Medicare "Part C," or "Medicare Advantage," provides Medicare beneficiaries with the option to receive their Medicare benefits (Parts A and B) through a wide variety of private managed care plans. Medicare "Part D" covered, among other things, certain prescription drugs.

- 43. Medicare "providers" included physicians, DME companies, independent clinical laboratories, and other health care providers who provided items or services to beneficiaries. To bill Medicare, a provider is required to submit a Medicare Enrollment Application Form ("Provider Enrollment Application") to Medicare. The Provider Enrollment Application contains certifications that the provider was required to make before the provider could enroll with Medicare. Specifically, the Provider Enrollment Application requires the provider to certify, among other things, that the provider would abide by the Medicare laws, regulations, and program instructions, including the Federal Anti-Kickback Statute, and that the provider would not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare.
- 44. A Medicare "provider number" is assigned to a provider upon approval of the provider's Medicare Enrollment Application. A health care provider that receives a Medicare provider number was able to file claims with Medicare to obtain reimbursement for items or services provided to beneficiaries.
- 45. A Medicare claim is required to contain certain important information, including: (a) the beneficiary's name and Health Insurance Claim Number ("HICN"); (b) a description of the health care benefit, item, or service that was provided or supplied to the beneficiary; (c) the billing codes for the benefit, item, or service; (d) the date upon which the benefit, item, or service was provided or supplied to the beneficiary; (e) the name of the referring physician or other health care

provider; and (f) the referring provider's unique identifying number, known either as the Unique Physician Identification Number ("UPIN") or National Provider Identifier ("NPI"). The claim form could be submitted in hard copy or electronically via interstate wire.

- 46. When submitting claims to Medicare for reimbursement, providers are required to certify that: (1) the contents of the forms were true, correct, and complete; (2) the forms were prepared in compliance with the laws and regulations governing Medicare; and (3) the items and services that were purportedly provided, as set forth in the claims, were medically necessary.
- 47. Medicare claims are required to be properly documented in accordance with Medicare rules and regulations. Medicare would not reimburse providers for claims that were procured through the payment of kickbacks and bribes.
- 48. Medicaid is a federal health care benefit program designed to provide medical services, equipment, and supplies to certain individuals and families with low income pursuant to the Social Security Act (Title 42, United States Code, Section 1396, *et seq.*). Medicaid is a health care benefit program as defined in 18 U.S.C. § 24(b).
- 49. Submission of a claim to a health care benefit program, whether public or private, involves representations by the provider that the services rendered were of a quality that met professionally recognized standards which include: (1) informed consent; (2) being medically necessary; and (3) being supported by documentation of such necessity.

State of Maine Prescription Monitoring Program

50. The State of Maine, Department of Health and Human Services, Office of Behavioral Health administers the Prescription Monitoring Program ("PMP"). The PMP is a secure database that is used across the State of Maine to improve public health by providing information about a patient's drug use for medical providers to access prior to prescribing or

dispensing those drugs. Prescription dispensers (such as Maine pharmacies, mail-service pharmacies, remote-dispensing pharmacies, and other dispensers) upload prescribing data to the PMP. From there, licensed prescribers (and delegates of licensed prescribers) have access to the PMP data. All prescribers and dispensers are required to register as data requesters. Dispensers are required, no later than the close of business on the next business day after dispensing a controlled substance, to submit certain information to the PMP, such as dates the prescription was filled and delivered, prescription number, the National Drug Code ("NDC") for the drug dispensed, quantity dispensed, dosage, and certain patient identifiers. With some exceptions, prescribers are required to check the PMP system for records related to the person for whom the medication is being prescribed, including a review of the Aggregate Morphine Milligram Equivalent for the person, the number of prescribers currently prescribing controlled substances to the individual, and the number of pharmacies currently filling prescriptions for controlled substances for that individual.

- IV. PROBABLE CAUSE TO BELIEVE NORRIS UNLAWFULLY DISTRIBUTED CONTROLLED SUBSTANCES OUTSIDE THE USUAL COURSE OF PROFESSIONAL PRACTICE AND NOT FOR A LEGITIMATE MEDICAL PURPOSE
- 51. As set forth below, there is probable cause to believe that NORRIS knowingly provided prescriptions for opioids and other controlled substances to patients requesting them, when there was no legitimate medical need for them and that she also submitted claims to Medicare and Medicaid for medically unnecessary services.

Claims Data Analysis

52. According to a preliminary review of Medicare data, NORRIS is in the 99th percentile among all prescribers in the country for the total MMEs prescribed per patient. In the state of Maine, specifically, she has the highest MME prescribing rate per patient.

- 53. The Medicare data indicates that NORRIS is in the 95th percentile for a number of outlier behaviors that are indicative of illegal prescribing, including, among others: the total MME prescribed by a physician (NORRIS is highest in Maine for total MMEs prescribed); the total MME for oxycodone specifically; the total payments for oxycodone; and both the average and median MME prescribed per patient.
- 54. The Medicare data also suggests that NORRIS wrote prescriptions that were funded under Medicare Part D to approximately 185 patients with whom she did not have any previous Medicare claims for treatment under Part A or Part B. Based on my training and experience, this data suggests that NORRIS does not have a prior doctor-patient relationship with these patients, which is an additional red flag indicative of illegal prescribing practices.
- 55. Additionally, NORRIS is in the 95th percentile for her prescribing to patients both an opiate and a benzodiazepine (such as clonazepam). From my training and experience and information relayed to me by other members of the investigative team, I know that the prescribing of both an opiate and a benzodiazepine is a well-known combination of controlled substances that is commonly abused and/or diverted by patients. Further, I know that the preliminary analysis of NORRIS's Medicare data—as outlined above—is indicative of illegal prescribing practices.

Walmart's Refusal to Fill

56. Due to her overall prescribing practices, NORRIS has been "centrally blocked" by Walmart, Inc. ("Walmart") as of November 3, 2021. This central block ensures that Walmart's pharmacy locations are prohibited from filling prescriptions written by NORRIS. According to an internal investigation performed by Walmart Global Investigations, Walmart performed an analysis of NORRIS's prescribing practices between October 2020 and October 2021. During those twelve months, NORRIS's top-prescribed drugs were methadone, Suboxone, and

oxycodone.

- 57. As part of that investigation, Walmart identified a number of "red flags" in NORRIS's prescribing practices, including, among others: evidence of "pharmacy shopping" (that is, one patient traveling to multiple pharmacies to fill prescriptions); total number or percentage of controlled substances prescribed; patients insisting on paying for their prescriptions refills with cash; unusually large quantity or high starting dose for the prescription; and providing the same diagnosis for a majority of her patients.
- 58. According to guidance from the CDC, in order to minimize the risk of potential overdose, medical professionals prescribing opioids should use a threshold prescription rate of 90 MME for safely prescribing opioids.⁷ According to Walmart's investigation, NORRIS prescribed the average patient approximately 174 MMEs per day.

Board of Osteopathic Licensure

59. On June 16, 2022, the State of Maine Board of Osteopathic Licensure provided a letter to NORRIS notifying her that, after receiving a copy of Walmart's notice letter to NORRIS, it had independently reviewed five patients' records from NORRIS's office. The Board of Osteopathic Licensure determined that three of those five patients were on high doses of methadone, with two on benzodiazepines, without any plan to taper those medications, as part of NORRIS's treatment of their drug dependency. The letter specifically cites that NORRIS may be violating the Board's standards for professional conduct and the Board's rules regarding the use of controlled substances in the treatment of pain.

⁷ See Calculating the Total Daily Dose of Opioids for Safer Dosage, Centers for Disease Control and Prevention (available at https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf).

Expert's Analysis

- 60. As part of the government's investigation into the complaints regarding NORRIS's prescribing practices, medical expert Donald Sullivan, RPh, PhD (Dr. Sullivan) was consulted. Dr. Sullivan is a Professor of Pharmacy Practice and Science at The Ohio State University. He is a Professor of Clinical Pharmacy at The Ohio State University College of Pharmacy, and received his bachelor's, master's, and doctorate degrees from The Ohio State University's College of Pharmacy. Dr. Sullivan has been teaching in pharmacology for more than twenty years. He has received the P3 Distinguished Teaching Award and the Miriam R. Balshone Award for Distinguished Teaching. Dr. Sullivan has been published in approximately twenty peer-reviewed publications.
- 61. As part of the investigation, Dr. Sullivan reviewed NORRIS's controlled substance prescribing patterns from approximately May 2020 to May 2022.
- 62. Dr. Sullivan opined that NORRIS wrote thousands of prescriptions for narcotic pain killers, benzodiazepines, and stimulants that were not for a legitimate medical purpose. Consequently, Dr. Sullivan believes that many of NORRIS's patients were put at "extreme risk of overdose," based on NORRIS's prescriptions.
- 63. Specifically, Dr. Sullivan notes that NORRIS frequently prescribed methadone and oxycodone to be taken at the same time. According to Dr. Sullivan, a two-narcotic-pain-killer combination is frequently used by patients abusing or diverting controlled substances. Dr. Sullivan also notes that NORRIS prescribed patients both narcotic pain killers and a benzodiazepine to be taken at the same time, including some patients who were prescribed two narcotic pain killers and a benzodiazepine. Patients taking this combination are four times more likely to overdose than patients who are prescribed a single narcotic pain killer.

- 64. Dr. Sullivan determined that NORRIS's prescribing practices put her well above the CDC guidance of 90 MMEs per day, and Maine's guidance of 100 MMEs per day, as many of her patients were prescribed over 300 MMEs, with a few over 1,000 MMEs. For example, Patient J.A. was prescribed both methadone and hydromorphone, with a total MME of 1200–1360. Dr. Sullivan opined that this placed Patient J.A. at "imminent risk for an overdose." One patient was prescribed two narcotic pain killers (methadone and oxycodone), with a total MME of 1500–1740, as well as a benzodiazepine (diazepam). Again, Dr. Sullivan opined that this placed patient at "imminent risk of an overdose." Another patient, B.D., was prescribed three narcotic pain killers (fentanyl and two forms of hydromorphone), including the "highest dose" Dr. Sullivan has "ever seen prescribed of hydromorphone," with a total MME of 1664. In addition to these narcotic pain killers, this patient was prescribed benzodiazepine, putting Patient B.D. at "imminent risk for an overdose."
- 65. Dr. Sullivan determined that at least twenty-four of NORRIS's patients were prescribed two narcotic pain killers and a benzodiazepine at the same time.
- 66. According to Dr. Sullivan, most prescribers write prescriptions for roughly four weeks or one month of the medication. However, NORRIS frequently writes prescriptions for between seven and fifteen days. Dr. Sullivan notes that the shorter prescription supply ensures that the patient will have to return to the doctor more frequently for refills, allowing the provider to bill for more frequent office visits. Dr. Sullivan determined that NORRIS wrote seven-day prescriptions for at least 55 patients between May 2020 and May 2022. From my training and experience, as well as information relayed to me by other members of the investigative team, I know that this prescribing tactic is a well-known red flag of illegal prescribing.
 - 67. Exhibit 1 provides list of patients that Dr. Sullivan concluded that NORRIS

prescribed controlled substances to outside the usual course of professional practice and not for a legitimate medical purpose.

Patient Deaths

- 68. According to the Medicare and Medicaid data, between January 2018 and June 2022, approximately twenty-two of NORRIS's patients, who were covered by Medicaid, died. Among those twenty-two patients, the average age was roughly 49 years old. During that same time period, nine of NORRIS's patients, who were covered by Medicare, died. The average age of those deceased Medicare beneficiaries at the time of death was 68 years old.
- 69. The investigation team has received incident reports and medical examiner reports for at least seven of NORRIS's patients whose primary cause of death was determined to be an overdose. One of these patients died of an overdose in March 2022—within a few weeks of receiving a methadone prescription from NORRIS. According to a toxicology report recovered from the Maine Office of Chief Medical Examiner, this patient tested positive for caffeine, THC, methadone, and a methadone metabolite (meaning that patient's body had begun processing the methadone). The Office of Chief Medical Examiner determined the cause of death to be "acute methadone intoxication."
- 70. Additionally, data revealed that NORRIS prescribed controlled substances to of overdoses who died within 45 days of receiving a controlled substance prescription from NORRIS. These patients are among those identified in Exhibit 1.

UPIC Investigation

71. On September 1, 2021, the Uniform Program Integrity Contractor for the New England region, on behalf of CMS, opened an investigation into NORRIS to review suspicion of opioid over-prescribing, opioid drug diversion, and prescribing medically unnecessary opioids.

- 72. On February 25, 2022, as part of that investigation, the UPIC issued a letter notifying NORRIS of the investigation and seeking certain patient files and records for eleven patients.
- 73. In response to the UPIC's letter, on or around April 28, 2022, NORRIS executed and submitted to the UPIC a Provider Intake Questionnaire and produced patient files.
 - 74. From there, the UPIC retained a medical consultant to:

Review [NORRIS]'s professional claims to determine if the services rendered justify the opioids prescribed per the pharmacy billing. The sample consists of 11 recipients with the highest MMEs that met the most flagged criteria. Review to determine if services rendered and opioids prescriptions were medically necessary and if urinary drug testing was ordered and used in medical decision making with regard to prescribing opiates.

- 75. On or about June 29, 2022, following a review and analysis of NORRIS's claims and patient files, the UPIC's medical consultant issued a Consultant Statement. As a preliminary matter, the consultant noted that "while much of the documentation for the cases requested was not provided, evidence for the allegations of concern was apparent from the limited documentation provided. The allegations that [NORRIS] is engaging in opioid over-prescribing and prescribing opioids while not medically necessary are well founded." A summary of the consultant's findings are set forth below:
 - i. In many instances NORRIS prescribed dangerously high doses of opioids beyond what is recommended by the CDC for safe opioid prescribing;
 - ii. NORRIS prescribed high dose opioids with benzodiazepines which increases risk for overdose especially in patients with opioid use disorders;
 - iii. NORRIS prescribed high-dose, short-acting opioids to patients with severe opioid-use disorders, which is contraindicated;
 - iv. NORRIS managed patients with severe opioid-use disorders with methadone at higher doses than standard pain management doses and more appropriate for management of an opioid use disorders, which is illegal outside of a federally qualified methadone maintenance program;
 - v. For patients with opioid-use disorders, NORRIS documented very little evidence-based counseling;

- vi. NORRIS prescribed Adderall to patients with substance-use disorders based on the patients' reports of inattention without documenting and formal testing or collaboration with therapists;
- vii. NORRIS prescribed Adderall to one patient as needed, which is off label, who intermittently used cocaine, which is contraindicated;
- viii. NORRIS upcoded E/M codes in many of the medical records that were reviewed and therefore have been reduced;⁹ and
 - ix. Many of the E/M codes were denied due to the NORRIS's failure to provide documentation for the dates of service in question.
- 76. Investigators obtained a copy of the patient files that NORRIS submitted to the UPIC. Many of the documents contained within the patient files include medical records and charts that were stored and maintained with the electronic health record vendor Elation. Exhibit 1 contains a list of patient files that were also analyzed by the UPIC:
- 77. On September 23, 2022, *In the Matter of the Search of Information Associated with Account #4039414185988 (Merideth Norris) Stored at Premises Controlled by Elation Health, Inc.*, 2:22-mj-166-KFW, U.S. Magistrate Judge Karen Frink Wolf issued a search warrant allowing the government to search and seize certain electronic medical records from Elation Health, Inc. NORRIS, through GRACEFUL RECOVERY, contracted with Elation Health, Inc. to keep and maintain electronic medical records for her patients.
- 78. As part of the investigation, the government received initial returns from Elation Health, Inc., containing complete patient files for sixteen patients—each of which were identified through PMP, UPIC records, police reports, or records obtained from the Board of Osteopathic Licensure as receiving prescriptions for controlled substances that appear to have been issued by NORRIS outside the usual course of professional practice and not for a legitimate medical practice. Patient files obtained are included in Exhibit 1.

⁸ Elation Health, Inc. is in the process of shipping a hard drive to investigators containing complete returns from the search warrant application, which will include electronic medical records related to all of NORRIS's patients treated at GRACEFUL RECOVERY.

⁹ "E/M codes" are evaluation and management codes used to represent services provided by a physician or other qualified healthcare professional.

- 79. The patient files contain "Visit Notes," "Nonvisit Notes," urine drug screen analysis results, internal messages amongst NORRIS and her support staff, executed Controlled Substance Agreements between NORRIS and the patient, and other medical records—such as records from other treating physicians or providers. Investigators have reviewed select patient files from the above list and identified a number of red flags with NORRIS's prescribing practices. Most notably, NORRIS is prescribing dangerously high amounts of controlled substances—often times far exceeding the CDC's guidelines related to MME and often combining opioids, benzodiazepines, and stimulants. She is also issuing these prescriptions to patients who have a documented history of diverting or abusing controlled substances.
- 80. For instance, according to received records, Patient C received prescriptions for methadone (10mg 8-10x daily), hydromorphone (4mg 4-5x daily), chlordiazepoxide (25b 3x daily), and diazepam (5mg 4x daily) yielding an MME of, at times, approximately 1144—over ten times the recommended dosage from the CDC. Patient C received these prescriptions despite the fact that Patient C repeatedly tested positive for additional illicit drugs (such as cocaine, Xanax, and marijuana) in Patient C's urine drug analysis, and also after NORRIS received a call informing NORRIS that Patient C was diverting her prescriptions to her boyfriend (also one of NORRIS's patients).

Expert Review of Patient Files

- 81. The government retained Dr. Shonali Saha to review patient files from NORRIS's electronic medical records as well as PMP data for select patients, including records related to patients, including Patient A, Patient B, and Patient C.
- 82. **Patient A** Dr. Saha noted that NORRIS prescribed Patient A. oxycodone (opioid), dextroamphetamine-amphetamine (stimulant), and clonazepam (benzodiazepine), while also

treating Patient A with methadone maintenance. Further, Dr. Saha noted that, in December 2021, Patient A attempted to kill himself and overdosed on prescriptions NORRIS issued, and that he also admitted to using cocaine along with his prescription drugs. Despite these red flags, NORRIS did not follow any safety planning. Instead, later that month, on December 23, 2021, NORRIS prescribed Patient A the same three-drug combination—merely reducing the clonazepam prescription from 1mg to 0.5mg tablets. Dr. Saha concluded this combination of prescriptions was outside the usual course of professional practice and not for a legitimate medical purpose.

- 83. **Patient B** For years, NORRIS prescribed Patient B.—a 74-year-old female, who weighed approximately 121 pounds—extended release Oxycontin 80mg tablets combined with a muscle relaxer, and Ambien. Dr. Saha concluded these prescriptions put Patient B at "incredibly high risk of overdose" and Dr. Saha was surprised that Patient B "is still alive." Dr. Saha explained that she was additionally concerned because Patient B was elderly, and opioids affect her liver function. Dr. Saha also noted that there was little clinical information in the patient file. Ultimately, Dr. Saha concluded that Oxycontin prescriptions issued by NORRIS to Patient B and filled on or around March 24, 2022, April 21, 2022, and May 20, 2022, were outside the usual course of professional practice and not for a legitimate medical purpose.
- 84. Patient C NORRIS prescribed Patient C a three-drug combination of methadone (opioid), hydromorphone (opioid), and diazepam (benzodiazepine), which had a total MME in excess of 1280 per day—over 12x the recommended MME by the CDC. Additionally, Patient C was diagnosed with Hepatitis C, which affected her liver function and ability to clear the medication. As a result, Patient C's liver was performing poorly and Patient C therefore experienced an increased dosage over what was actually prescribed. Patient C. also tested positive for cocaine, but NORRIS did not address the cocaine use in Patient C's patient file. Instead,

NORRIS continued to prescribe Patient C. this three-drug combination. Dr. Saha concluded that prescriptions issued by NORRIS to Patient C and filled on or around June 16, 2022, June 17, 2022, and June 21, 2022, were outside the usual course of professional practice and not for a legitimate medical purpose.

- 85. Based on foregoing, there is probable cause to believe that, from January 1, 2019, to present, NORRIS has committed, and is continuing to commit, violations of 21 U.S.C. § 841(a) (1) (illegal drug distribution).
- 86. Specifically, based on the evidence set forth above, there is probable cause to believe that NORRIS unlawfully distributed controlled substances to the patients listed in Exhibit 1.

V. PROBABLE CAUSE TO BELIEVE NORRIS COMMITTED HEALTH CARE FRAUD AND/OR SOLICITING AND RECEIVING ILLEGAL KICKBACKS

- 87. Among the health care benefits, items, and services that are covered by insurance programs, such as Medicare and MaineCare, are office visits and services and procedures provided by third parties, such as urine drug testing and prescription drugs.
- 88. Providers, such as NORRIS, who participate in these insurance programs, either by rendering services or ordering services, must adhere to all relevant regulations of the insurance programs, or those of their third-party intermediaries through which claim payments may be received, adjudicated, and paid. Among these regulations are that providers may only submit or order claims for medical services which are reasonable and medically necessary.
- 89. As part of her enrollment with MaineCare, NORRIS executed—on a number of occasions and most recently on January 3, 2019—the MaineCare/Medicaid Provider Agreement ("Provider Agreement").
 - 90. NORRIS agreed within the Provider Agreement "to comply with the provisions of

the Federal and State laws and regulations related to Medicaid," among other conditions. NORRIS also certified that she nor any of her employees or agents "engaged in any activities prohibited by 42 U.S.C.§ 1320a-7b [(the Federal Anti-Kickback Statute)]." NORRIS also specifically agreed to the following:

Prohibition of Rebate, Refund, or Discount (Kickbacks)

- a) [NORRIS] will not offer, give, furnish, or deliver any rebate, refund, commission, preference, patronage dividend, discount or any other gratuitous consideration in connection with the rendering of services to a Member.
- b) The Provider will not solicit, request, accept or receive any rebate, refund, commission, preference, patronage, dividend, discount or any other gratuitous consideration in connection with the rendering of services of any Member or take any other action or receive any other benefit prohibited by 42 U.S.C. § 1320a-7b
- 91. NORRIS also agreed to, and was informed through the Provider Agreement, that MaineCare reimbursement was "contingent on [NORRIS's and her agents' and employees'] compliance with applicable Federal and State Medicaid" laws and regulations and that NORRIS will only be reimbursed for "medically necessary care and services actually provided"
- 92. NORRIS made similar certifications to Medicare. Specifically, in order to bill Medicare, a provider must submit a Medicare Enrollment Application Form CMS-855B ("Provider Enrollment Application") to Medicare. The Provider Enrollment Application contains certification statements that the provider must agree to before enrolling with Medicare. The certification statement sets forth, in part, that the provider agrees to abide by the Medicare laws, regulations, and program instructions, including the Federal Anti-Kickback Statute, and will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare.
 - 93. Based on the foregoing, there is probable cause to believe that NORRIS submitted

claims to Medicare and MaineCare (Medicaid) for services that were not medically necessary and not subject to reimbursement, and also referred laboratory services to Millennium in exchange for illegal kickbacks and renumeration.

<u>UPIC Evidence of Upcoding and Billing for Medically Unnecessary Services</u>

94. As discussed above, the UPIC conducted an investigation into NORRIS's prescribing practices and claims submitted related to a sample of her practice (eleven patients listed above). The UPIC selected these eleven patients because they had "the highest MMEs that met the most flagged criteria," and reviewed the claims to "determine if services rendered and opioids prescriptions were medically necessary and if urinary drug testing was ordered and used in medical decision making with regard to prescribing opiates." As summarized above, the UPIC's medical consultant concluded that NORRIS "is engaging in opioid over-prescribing and prescribing opioids while not medically necessary" The medical consultant also found that NORRIS "is upcoding E/M codes of in many of the medical records" and "[m]any of the E/M codes were denied due to the failure of the provider to provide documentation for the dates of service in question."

Renumeration from Millennium for Urine Drug Screening Referrals

- 95. Additionally, according to electronic medical records obtained by search warrant, NORRIS's patients were subjected to urine drug screening or testing, and NORRIS referred the testing to Millennium, a lab based in California.
- 96. According to Medicare claims data, from January 3, 2018, through June 8, 2022, NORRIS referred to Millennium approximately 154 patients, totaling 1,329 claims for urine drug screening, which resulted in Millennium submitting approximately \$604,323 in claims to Medicare, of which Medicare paid Millennium approximately \$262,892.

- 97. According to MaineCare claims data, from January 1, 2019, through October 19, 2022, NORRIS referred to Millennium urine drug screening for 4,208 claims, which resulted in Millennium submitting approximately \$962,413 in claims to Medicare, of which Medicare paid Millennium approximately \$239,788.
- 98. On October 17, 2022, investigators interviewed a former employee of GRACEFUL RECOVERY. This employee worked part-time in an administrative role for approximately five years, through in or around February 2022. This employee informed investigators that NORRRIS referred urine drug screening and testing to Millennium. This employee stated that Millennium embedded an employee at GRACEFUL RECOVERY and that the employee was present whenever GRACEFUL RECOVERY was open. The employee worked as a urine collector. When patients were due for a urine drug screen or test, the patient reported to the urine collector from Millennium, who administered the screen.
- 99. The investigation indicates NORRIS referred medically unnecessary services to Millennium in exchange for kickbacks. Review of medical records and an interview with former employee indicate that these services were typically ordered by an embedded employee paid by Millennium working at GRACEFUL RECOVERY.¹⁰
 - 100. Notwithstanding this high level of testing, purportedly to guard against patient

¹⁰ On or around October 19, 2015, Millennium entered into two settlement agreements with the Department of Justice and agreed to pay \$256 million to resolve allegations that Millennium billed Medicare, Medicaid, and other Federal health care programs for medically unnecessary drug testing and genetic testing, and provided kickbacks to physicians to induce business. In the underlying complaint filed in United States of America, et al. v. Millennium Laboratories of California, et al., 1:09-cv-12209-NMG (D. Mass.), the United States alleged that Millennium caused physicians to order excessive numbers of urine drug tests, in part through the promotion of "custom profiles," which, instead of being customized for individual patients, were in effect standing orders that caused physicians to order large number of tests without an individualized assessment of each patient's needs. Millennium's use of the so-called "custom profile" led to the over-billing of Federal health care programs which limited payment to services that are reasonable and medically necessary for the treatment and diagnosis of an individual patient's illness or injury. The United States also alleged that Millennium violated the Stark Law and Federal Anti-Kickback Statute by providing physicians with free drug test cups on the express condition that the physicians return the specimens to Millennium for hundreds of dollars' worth of additional testing.

misuse and diversion, NORRIS, appears to have routinely ignored the results of these tests. For instance, according to electronic medical records, on June 2, 2022, Patient C had an office visit with NORRIS, during which someone at GRACEFUL RECOVERY collected a urine sample from Patient C. At that time, NORRIS was prescribing to Patient C a combination of hydromorphone, diazepam, and methadone. NORRIS referred the urine drug screen to Millennium for testing. According to the results, Patient C tested positive for the prescribed controlled substances as well as for cocaine, Xanax (not prescribed), and marijuana. NORRIS received the results on or around June 5, 2022. Despite these results, on June 10, 2022, NORRIS issued Patient C a prescription for hydromorphone, and then on June 16, 2022, NORRIS issued Patient C prescriptions for diazepam and methadone. From there, NORRIS continued to issue Patient C routine prescriptions for this three-drug cocktail despite Patient C's nonadherent urine drug screening results.

- 101. Based on my training and experience, I know that it is a violation of the Anti-Kickback statute when a laboratory, such as Millennium, provides a clinic, such as GRACEFUL RECOVERY, with staff to act as an office worker or office manager to perform services and complete tasks to support the practice, such as answering phones, scheduling patient visits, collecting co-payments, resolving computer issues, taking vital signs, and other prohibited services (collectively "prohibited services"). I know that if Millennium was paying the salaries of this urine collector to perform prohibited services for GRACEFUL RECOVERY, then such would be a violation of the Federal Anti-Kickback Statute.
- 102. Based on the foregoing, there is probable cause to believe that Millennium was paying an employee to work as a urine collector at GRACEFUL RECOVERY. As the urine collector was present at GRACEFUL RECOVERY at all times the practice was open, there is probable cause to believe that the urine collector performed prohibited services, which constitute

illegal kickbacks and remuneration to NORRIS and her practice, GRACEFUL RECOVERY. As a result, there is probable cause to believe that evidence of this arrangement between NORRIS/GRACEFUL RECOVERY and Millennium will be found at GRACEFUL RECOVERY as well as evidence of the job duties and responsibilities of the urine collector working at GRACEFUL RECOVERY.

VI. PROBABLE CAUSE THAT EVIDENCE IS LOCATED AT TARGET LOCATION (GRACEFUL RECOVERY)

- 103. Based on the above and below facts, there is also probable cause to believe that the records and evidence sought, as more fully described in Attachment B, are located at the **TARGET LOCATION**, as more fully described in Attachment A.
- 104. Based on my training and experience, it is standard practice for documents to be kept by medical offices in the normal course of business that pertain to daily billing, accounts received, bank records, deposit receipts, telephone records, appointment books, and sign in sheets. These financial records and billing documents often contain evidence to establish that patients have consulted with the doctor or have received prescriptions from the doctor.
- 105. Based on my training and experience, I know that providers such as NORRIS often retain medical records for many years, in the event patient medical records are requested by another physician, the provider is sued by a patient, and/or an insurance plan seeks to conduct an audit.
- 106. Additionally, despite the fact that NORRIS keeps and maintains electronic medical records, based on my training and experience, I know that providers, such as NORRIS, in some instances keep and maintain both electronic medical records as well as a hard copy patient file at their practice. Also, in reviewing electronic medical records obtained pursuant to search warrant, NORRIS has indicated in Visit Notes and other medical records that she is treating patients at GRACEFUL RECOVERY as well as at CAP Quality and other methadone "clinics." As a result,

there is probable cause that NORRIS may keep and maintain patient files related to her associated practices (Savida Health, CAP Quality, and Enso Recovery) at GRACEFUL RECOVERY.

- 107. The medical-legal purpose that a physician or provider would keep and maintain patient files include: (i) a physician is potentially open to medical malpractice suits for three years from the date the medical error was committed; (ii) a physician is potentially open to civil False Claims suits for up to six years from the date of the billing in question (31 U.S.C. § 3731); and (iii) a similar period applies to actions by HHS-OIG. HHS-OIG can initiate actions against physicians who, among other things, submit prohibited claims under Federal health care programs, such as Medicare, from six years from the date on which the claim was presented, the request for payment was made, or the incident occurred (42 C.F.R. Part 1003).
- as set out below. Under Medicare rules, a physician who contracts to provide or supply covered ordered items of . . . [a] clinical laboratory . . . is required to maintain medical records for seven years from the date of service. Failure to do so results in the revocation of billing privileges. 42 C.F.R. § 424.516(f). MaineCare requires that providers keep medical records for a period of five years plus the current year.
- 109. NORRIS operates a functioning medical office at the **TARGET LOCATION**. The seizure of GRACEFUL RECOVERY's records and hard copy patient files may limit GRACEFUL RECOVERY's ability to conduct whatever business they continue to conduct. As with any search warrant, I expect that this warrant will be executed reasonably. Reasonable execution will likely involve conducting an investigation on the scene of what evidence, records, and patient files must be seized or copied. Where appropriate and if feasible, efforts will be made to copy records or patient files rather than physically seize items to reduce the extent of disruption

to the office.

GRACEFUL RECOVERY remains open for business at the TARGET 110. LOCATION, which shares its building location with other businesses. Accordingly, law

enforcement will be as efficient as possible in seizing the evidence sought herein so as not to

disrupt other businesses operating out of a different part of the building in which the TARGET

LOCATION is located.

CONCLUSION

111. Based on the foregoing, there is probable cause to believe that NORRIS has

committed the TARGET OFFENSES, including violations of 21 U.S.C. § 841. There is also

probable cause to believe that evidence, fruits, and instrumentalities of those TARGET

OFFENSES, as outlined in Attachment B, will found at the **TARGET LOCATION** (Merideth C.

Norris, P.A. d/b/a Graceful Recovery, 58 Portland Road, Suite 18, in Kennebunk, Maine 04043),

as described more fully in Attachment A.

Dale Wengler, Special Agent

Federal Bureau of Investigation

Sworn to telephonically and signed electronically in accordance with the requirements of Rule 4.1 of the Federal Rules of Criminal Procedures

Date: Oct 25 2022

City and state:

Portland, Maine

Nancy Torresen, U.S. District Judge

Printed name and title

ATTACHMENT A

Property to be Searched

This warrant applies to information associated with medical and other records maintained at Merideth C. Norris, P.A. d/b/a Graceful Recovery, 58 Portland Road, Suite 18, in Kennebunk, Maine 04043 (the "TARGET LOCATION").

The **TARGET LOCATION** is described as a multi-unit commercial building within the Kennebunk Professional Center, as depicted below. The office entrance is below grade (about a half of a flight of stairs down from ground level).





ATTACHMENT B

Particular Things to be Seized

I. <u>ITEMS TO BE SEIZED</u>

For the period of at least January 1, 2019, through the present (except where outlined below), any and all of the following records concerning or related to NORRIS or any employee or agent, known or unknown, who is reasonably believed to be part of alleged violations of federal law, including but not limited to 21 U.S.C. § 841, 18 U.S.C. § 1347, or 42 U.S.C. § 1320a-7b, or a beneficiary of any proceeds of the alleged violations of federal law.

- 1. All records, regardless of when they were created, related in any way to the patients listed in **Exhibit 1**, including, without limitation, the following type of records: patient charts, files, records, superbills, invoices, treatment cards, prescription records, dispensing orders, patient ledger cards, patient complaints, patient sign-in sheets, provider notes, medical assistant and staff notes, certificates of medical necessity, diagnostic test notes or reports, original patient or referral source listings.
- 2. Records and information relating to contracts, agreements, papers, and affiliated records constituting, concerning, or relating to the provision of prescriptions for controlled substances by NORRIS, and/or any other clinician, employee, or other individuals affiliated in any way with Merideth C. Norris, P.A. d/b/a Graceful Recovery, Enso, LLC, Savida Health, PC, or CAP Quality Care, Inc.
- 3. All financial and tax-related books, records, and documents, including, without limitation:
 - a. Bank accounts, money market accounts, checking accounts, equity line of credit, investment accounts, stock fund accounts, bonds or bond funds; including deposits and disbursements, cancelled checks or drafts, electronic transfers, ledgers, loan statements, and loan agreements relating to Merideth C. Norris, P.A. d/b/a Graceful Recovery, Enso, LLC, Savida Health, PC, or CAP Quality Care, Inc.;
 - b. Bank accounts, money market accounts, checking accounts, equity line of credit, investment accounts, stock fund accounts, bonds or bond funds; including deposits and disbursements, cancelled checks or drafts, electronic transfers, ledgers, loan statements, and loan agreements relating to the EFT accounts connected to Merideth C. Norris, P.A. d/b/a Graceful Recovery, Enso, LLC, Savida Health, PC, or CAP Quality Care, Inc.;
 - c. Credit/Automatic Teller Machine/Debit card accounts;

- d. All corporate, business, and personal tax returns, including, without limitation, any quarterly employment tax returns, withholding records, W-2s and any Internal Revenue Service Form 1099s;
- e. All loan and credit information, including, without limitation, any letters of credit, revolving credit arrangements, loans, loan applications, financing arrangements, factoring arrangements, promissory notes, leases, or any other documents concerning sources of borrowed funds, including any applications;
- f. All financial statements and credit reports; and
- g. All accounts payable and receivable records.
- 4. All documents consisting, concerning or relating to all current and former employees, including, without limitation, personnel files, employee rosters, names, addresses, telephone numbers, email addresses, time cards or similar records, expense reports, training information, certification verification, salary and compensation information, disciplinary records, licensure records, job applications, job descriptions, employment agreements and W-2 forms.
- 5. Records and information relating to calendars, sign-in sheets, daily planners, timesheets or records indicating work schedules of employees or contracted entities (workers) of Merideth C. Norris, P.A. d/b/a Graceful Recovery, Enso, LLC, Savida Health, PC, or CAP Quality Care, Inc.
- 6. All contracts, billing agreements, professional services agreements, or any other contracts between the above referenced individuals or businesses, and any other individual, company, provider or billing company.
- 7. Records and information relating to correspondence related to controlled substances, including, but not limited to, remittance advise statements, manuals, advisories, newsletters, bulletins, and publications.
- 8. Records and information relating to the prescribing of controlled substances including any and all labeling, packing, literature and inserts pertaining to these drugs.
- 9. Records and information relating to NORRIS's or her affiliated practices' enrollment with, and participating in, Medicare or MaineCare.
- 10. Records of control over other areas such as storage units where financial, medical, or other billing records may be maintained.

- 11. Records of control of the premises and things described, namely, utility bills, telephone bills, rent or lease records pertaining to or evidencing ownership or control of the premises to be searched.
- 12. All correspondence, including memoranda, protocols, letters, and electronic mailings (emails) concerning any of the records described in the previous paragraphs.
- 13. Records related to assets or items of significant value reasonably believed to be proceeds of the illegal activity described in the affidavit for this search warrant.
- 14. Records related to Millennium Laboratories, Inc., or any other clinical laboratory that NORRIS or her affiliated practices are conducting business with, including agreements, correspondence with principals, agents, employees, or contractors of the laboratories, statements, invoices, laboratory orders, and testing results.

Exhibit 1: Particular Patient Files to be Seized





